

## **REMARKS**

Claims 1, 3, 4, 6-11, and 13-23 are pending in this application. Claims 1, 3, 4, 6-11 and 13-23 are provisionally rejected on the grounds of obviousness-type double patenting over Application No. 11/376,983. Claims 1, 3, 4, 6-11 and 13-23 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Thompson et al. in view of U.S. Patent Number 5,545,201 to Helland et al. Reconsideration is respectfully requested in light of the following remarks.

### **Double Patenting Rejection**

The Examiner has provisionally rejected the claims in this application for obviousness-type double patenting over Application Number 11/376,983. Because this is the earlier filed application of the two, a terminal disclaimer is not required and the application is allowable once the other rejections are overcome; a terminal disclaimer will be filed in Application Number 11/376,983 (if necessary) upon allowance of the claims in that application. MPEP §804(I)(B)(1).

### **Rejection Under 35 U.S.C. §103**

Claims 1, 3, 4, and 6-23 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Thompson et al. in view of U.S. Patent Number 5,545,201 to Helland et al. Reconsideration is requested.

Applicants' respectfully submit that the pending claims are not obvious in light of Thompson et al. and Helland based on the unexpected results achieved with Applicants' claimed invention. Unexpected results exist, and the claims are therefore not obvious, where the properties in the claimed invention and the prior art differ to such an extent that the difference is classified as a difference in kind, rather than one of degree. In re Waymouth, 499 F.2d 1273, 1276 (CCPA 1974). The title of the Thompson et al. patent is "System for Inducing Tachycardia Utilizing Near-Field T-Wave Sensing". At column 8, lines 22-26, Thompson et al. state "It is seen that this lead provides a distinctive signal which provides a significant improvement for very near-field T-wave detection which, e.g., is important for enhancing the tachy-inducing effectiveness of this

invention." In addition, at column 8, lines 13-17, Thompson et al. state "By making the electrode spacing less than 1 mm, this electrode configuration provides excellent near field sensing of cardiac signals; it can be used in the atrium for P-wave and atrial repolarization sensing, as well as in the ventricular [sic] for R-wave and T-wave sensing."

As fully supported by the attached Declaration of Gene A. Bornzin, Ph.D, a lead such as that described by Thompson et al. does in fact achieve the result described in that patent, namely providing a sense signal that allows for detecting T-waves. As Dr. Bornzin states in his declaration, he tested a lead having the specifications described by Thompson et al., and found no significant T-wave attenuation for a tip-to-ring spacing of approximately 1.0 millimeter when compared with the T-wave amplitudes of a control embodiment having a tip-to-ring spacing of 10 millimeters.

In addition, as set forth in Dr. Bornzin's declaration, when the applicants' application was filed, the inventors believed that either a passive fixation or active fixation lead would function in a similar manner with respect to T-wave sensing, which is why they included the alternate embodiment shown in Figure 4. However, through testing performed after filing the application, the inventors unexpectedly discovered that only the active fixation embodiment significantly attenuated T-waves. Therefore, the claims have been amended to positively recite a "helical tip electrode" such that the passive fixation embodiment has been disavowed.

It is well settled that it is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works. Newman v. Quigg, 877 F.2d 1575 (Fed. Cir. 1989). The "invention" is defined by the claims, which have been amended so that they no longer encompass Figure 4. In addition, as clearly supported in Dr. Bornzin's declaration, embodiments such as that shown in Figure 4 of the subject application or as described in the Thompson et al. patent do not significantly attenuate T-waves. Furthermore, the Examiner's apparent disbelief that Applicants' claimed invention provides such completely different results compared to either the lead shown in Applicants' Figure 4 or Thompson et al.'s lead is further evidence of an

unexpected result, which supports allowance of the claims and withdrawal of the obviousness rejection based on those unexpected results.

Therefore, Dr. Bornzin's latest declaration addresses the following issues: 1) it sets forth the surface areas of the electrodes in the test lead and shows that they were based on the Thompson et al. description (showing that the lead as tested is as described by Thompson et al.), 2) it describes how the embodiment in Applicants' Figure 4 does not function as originally believed at the time of filing, and 3) it shows how T-wave attenuation is only achieved through a combination of both inter-electrode spacing and active fixation with a helical electrode (based on the evidence from all three declarations that have been presented). Therefore, it is respectfully submitted that all of the Examiner's issues have been addressed by the submitted declarations.

Conclusion

In light of the above remarks and the presently submitted declaration of Gene A. Bornzin, Ph.D, as well as the previously submitted declarations of Yougandh Chitre and Gene A. Bornzin, Ph.D, it is respectfully submitted that the application is in condition for allowance, and a notice of allowance is requested.

Respectfully submitted,

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Date

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